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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,542	10/11/2005	Yoshihito Hagawa	64291 (71719)	2577
21874	7590	07/22/2008	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			WARE, DEBORAH K	
P.O. BOX 55874			ART UNIT	PAPER NUMBER
BOSTON, MA 02205			1651	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/552,542	HAGAWA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 March 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 27-38,43,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 27-38,43,47 and 48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10/11/05 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/3/07 and 10/11/05</u> .                                     | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Claims 27-38, 43 and 47-48 are pending.

### ***Election/Restrictions***

Applicant's election **without** traverse of Group I, claims 27-38, 43 and 47-48 in the reply filed on March 11, 2008, is acknowledged. All non-elected claims have been canceled.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. This case is a 371 of PCT/JP04/05089 filed April 8, 2004, and the Japanese document from which foreign priority is claimed from is dated April 8, 2003.

### ***Preliminary Amendment***

The Preliminary Amendment filed October 11, 2005, has been received and entered.

### ***Information Disclosure Statement***

The information disclosure statements (IDSs) submitted on October 11, 2005 and April 3, 2007 have been received and entered. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Response to Amendment***

The amendment to the claims filed March 11, 2008, has been received and entered. Claims 27-38, 43 and 47-48 are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the

specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

- (b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
  - (1) The name and address of the depository;
  - (2) The name and address of the depositor;
  - (3) The date of deposit;
  - (4) The identity of the deposit and the accession number given by the depository;

- (5) The date of the viability test; (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
- (1) The accession number for the deposit;
  - (2) The date of the deposit;
  - (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
  - (4) The name and address of the depository.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-38, 43 and 47-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-38, 43, and 47-48 are rendered vague and indefinite for the recitation of “crushed product”, “a culture of the lactic acid bacterium”, “a residue of the culture” “a treated product” because it is not clear what these products are per se, nor how the culture differs from the bacterium itself which is also a component member of the group in claim 27.

Claim 28 is further rendered vague and indefinite for the recitation of “a whey protein derivative” and also “by neutralization culturing” since it is uncertain what

derivative is being claimed per se, and what is intended by the terminology "neutralization culturing". Perhaps the culturing is intended to mean bringing the culture to a neutral pH, however, no steps are claimed and it is also uncertain whether the claim is a product by process type claim or merely a product claim. The metes and bounds of the claim can not be determined. Also "to a medium" is unclear whether the bacterium is inoculated in a medium or not, what does "to a medium" mean per se.

Claims 43 and 47-48 are further rendered vague and indefinite for the recitation of "administering" because it is not certain how the feed supplement is being given to livestock since a feed supplement can be given orally or parenterally or both per se.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27, 36, 28 and 43 and 47-48 rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Raczek (US 2002/0146399).

Claims are drawn to a feed supplement comprising a lactic acid bacterium belonging to Lactobacillus gasseri and method of improving an intestinal flora comprising administering the feed supplement to a calf during weaning.

Raczek teaches a feed supplement comprising a lactic acid bacterium belonging to Lactobacillus gasseri, note abstract, page 2, columns 1-2, [0012], lines 2-3, [0013], lines 3-5, [0014], lines 1-2 and 10-11 and [0036], line 1, and page 3, column 1, [0054], lines 12-14 and [0055], lines 1-2 and method taught at page 4, column 2, claims 11 and 12-15, (especially note claim 13).

The claims are identical to the teachings of Raczek and hence, are considered to be anticipated by the cited reference. However, in the alternative that there is some difference between the claims and the teachings of the Racek reference then the

difference is considered to be so slight as to render the claims obvious over Racek. It would have been obvious in the alternative to one of ordinary skill in the art to select for a *Lactobacillus gasseri* strain, at the time the claimed invention was made because Racek clearly teaches that *Lactobacillus gasseri* strains are contained in a feed supplement for treating a calf and other livestock for improving their intestinal flora and further teaches that the *Lactobacillus gasseri* microorganism and hence strains thereof are probiotics as well.

Thus, to select for these to be contained in a feed supplement to treat a calf and use it during the rearing a calf is clearly an obvious modification of the disclosed because it performs the identical function, however, if it is different then its difference is considered to be so slight as to render the claim(s) obvious. In the absence of persuasive evidence to the contrary the claims are rendered *prima facie* obvious. Each of the claimed features as claimed in claims 27, 36, 38, 43 and 47-48 are taught or are suggested by Raczek. Hence, the claims are anticipated but alternatively are considered obvious if by a showing of evidence the strain is different then the strain is at least suggested by the cited prior art rendering the feed supplement obvious as well.

Claims 27-38, 43 and 47-48 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sobol et al (6953574).

Claims are discussed above and are further drawn to a feed supplement wherein the culture contained by it (the supplement) is obtainable by inoculating the bacterium to a medium containing whey protein and the treated product can be a freeze dried product and further the feed supplement contains an excipient which is a starch.

Sobol et al teach a feed supplement, note col. 5, lines 60-63, wherein the supplement contains *Lactobacillus gasseri* bacterium, note col. 5, lines 13, lines 29-35 and col. 7, line 62. The culture is obtained by adding the bacterium to a medium containing whey protein, col. 6, lines 45-46, 54-58 and col. 6, lines 65-67; and col. 7, lines 3-6, wherein a neutralization culturing is disclosed because the pH of the culture medium is held near 7.0 (i.e. 6.5), of which will neutralize the culture. Also note col. 7, lines 45-55 and 65-62. Also note col. 9, lines 9-19 wherein the sediment or treated product if you will is formed into a dried product wherein the treated product is lyophilized (i.e. freeze dried). The supplement is useful for treating intestinal diseases, note col. 10, lines 65-67. The supplement further comprises a milk component too, see col. 5, line 29. Further, the supplement is used on farms in animal husbandry, col. 5, lines 50-54, such as livestock, which can include young livestock and a calf.

The claims are identical to the teachings of Sobol et al and are, therefore, considered to be anticipated by the teachings of the reference. However, in the alternative that there is some difference between the teachings of Sobol et al and the instant claims then the claims are considered to be obvious; because the difference is so slight as to at least promote an expectation of successful results because one of skill would have been motivated by the teachings of Sobol et al.

The treatment of young livestock is common place in animal husbandry because of its relationship to animal rearing, and treating method using the disclosed supplement for a calf is inherent to the teaching of animal husbandry by Sobol et al. However, the treatment of a calf would in the alternative have been at least an obvious modification of

the cited prior art. Each of the claimed features are either disclosed and inherent to the teachings, or alternatively obvious over Sobol et al. The neutralization culturing is inherent to the teachings of a nearly neutral pH being obtained for the culture medium while preparing the supplement containing the fermented culture containing Lactobacillus gasseri and milk component. A treated product is further disclosed and can be dried by lyophilization which is a form of freeze drying or can be performed by drum drying. The treated product can be in liquid or dry form as well, note col. 1, lines 5-15. The milk component clearly reads on the claimed presence of an excipient ingredient.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1651  
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